HD02
Hemodialysis Monitor
(Version 1.xx)

For use with Transonic® H4E Flow/Dilution Sensors and HD02 software on a laptop computer
Protected under USA patents # 5,453,576; 5,595,182; 5,685,989
and International patent # EP 0 781 161 B1.

Delivered Blood Flow, Recirculation, Vascular Access Flow and Cardiac Output Measurements during Hemodialysis

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Intended Uses

The HD02 Hemodialysis Monitor is intended for use by trained medical personnel on patients receiving hemodialysis treatment.

Delivered Blood Flow
Blood flow delivered to the dialysis system is used to check the hemodialysis pump setting and to confirm that the patient receives the hemodialysis treatment prescribed by the attending physician.

Access Recirculation
The fraction of dialyzed blood immediately recirculating back through the access into the dialyzer is used for confirmation of proper dialysis needle placement, identification of inadvertently reversed blood lines, recognition of dialysis pump settings in excess of Access Flow, and estimation of hemodialysis delivery in AV accesses and dual lumen catheters.

Vascular Access Flow
Blood flow through the vascular access is used for surveillance of access patency (AV grafts and fistulas). A low flow or a substantial decrease in flow from an initial baseline measurement may indicate decreased patency of the vascular access.

Cardiac Output
Blood flow pumped by the heart is used for assessment of a patient's hemodynamic condition while undergoing hemodialysis. Cardiac Output measurements may be included as a routine measurement with other monitoring parameters in a vascular access monitoring program. High Access Flow (exceeding 2000 ml/min) and symptoms of cardiac dysfunction indicate the need for Cardiac Output measurements. If Access Recirculation is present, reducing dialysis pump flow (do not reduce pump flow to less than 100 ml/min) may eliminate the recirculation. If recirculation persists, cardiac output can't be measured. Cardiac Output can't be measured in patients with central catheters and require the use of the Flow-QC Tubing Segment (ADT1010-40) customized for Transonic measurements.

Contraindications

- Use only on hemodialysis patients under stable cardiovascular condition. Not for the unattended monitoring of patient conditions which could result in imminent danger to the patient.

- The H4E dual flow/dilution sensor is for use on sterile tubing only. Never use on arteries or veins.

- Not intended for fetal or ophthalmic use.
Warnings and Precautions

✓ See the list of the HD02’s intended uses and contraindications.
✓ For use only during hemodialysis.
✓ The company disclaims responsibility for all other uses, and the user agrees to assume liability for damages resulting from non-intended use or operator-error by the user or user's employees.
✓ Place flow/dilution sensors on flexible hemodialysis tubing only (never on arteries or veins).
✓ Safe and effective use of the Transonic HD02 Hemodialysis Monitor depends on correct application technique, adequate precaution and readiness for emergencies. Read manual prior to use.
✓ The HD02 Hemodialysis Monitor must be used only with H4E Transonic flow/dilution sensors.
✓ The HD02 Hemodialysis Monitor achieves a high degree of patient electrical isolation through the use of:
  • Hospital-grade isolation between power line and monitor.
  • Double insulation between electronics and flow/dilution sensor and flow/dilution sensor cable and its user-accessible parts.
  • Many factors may degrade or bypass this insulation:
    • Connections between the monitor and any external line-powered devices.
    • Connection of monitor to power line via non-hospital grade power cord.
    • Connection between the monitor and patient or patient circuits other than the supplied accessory flow/dilution sensors.
    • Damage to the electrical isolation of flow/dilution sensors or flow/dilution sensor cable.
✓ It is the user's responsibility to review the monitor and flow/dilution sensor use and conditions for compliance with local regulations.

<table>
<thead>
<tr>
<th>Legend Symbol</th>
<th>Definition</th>
<th>Transonic Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Attention, consult accompanying documents</td>
<td>The specific directions in this manual and in the package inserts included with each sensor must be observed. Periodic testing of sensors must be performed to assure the validity of flow measurements.</td>
</tr>
<tr>
<td>⚠️</td>
<td>Dangerous Voltage</td>
<td>The flow meter must not be modified or serviced except by qualified Transonic repair persons.</td>
</tr>
<tr>
<td>CE</td>
<td>CE Conformity Mark</td>
<td>This flow meter conforms to the requirements of applicable EU directives. See the Declaration of Conformity accompanying this equipment for specific directives.</td>
</tr>
<tr>
<td>Defibrillator Proof Type CF Equipment</td>
<td>Defibrillator Proof Type CF Equipment</td>
<td>This flow meter employs line-to-meter, meter-to-probe, and probe-to-patient (cardiac floating) isolation to yield a high degree of patient electrical protection.</td>
</tr>
<tr>
<td>Not Category AP Equipment</td>
<td>Not Category AP Equipment</td>
<td>Danger – Explosion risk if used with flammable anesthetics.</td>
</tr>
<tr>
<td>Equipotentiality</td>
<td>Equipotentiality</td>
<td>This ground stud is connected to the metal cabinet of the monitor. It provides the user with a means to equalize the electrical potential when connecting the monitor to other equipment.</td>
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I. Specifications

The Transonic HD02 Hemodialysis Monitor System (Figure 1) consists of an electronic flowmeter, clamp-on flow/dilution sensors for extracorporeal use on dialysis tubing, and a PC-compatible laptop computer loaded with HD02 software for patient trending and automatic computation of Access Recirculation, Access Flow and Cardiac Output. Ultrasound transit-time techniques are used to measure Delivered Blood Flow, while indicator dilution methods are used to calculate Access Recirculation, Access Flow, and Cardiac Output. Cardiac Output measurements require the use of an injection port customized for Transonic measurements and a method to warm saline.

**Electronic Flowmeter**

Displays ultrasound signal intensity and Delivered Blood Flow in the arterial line on a 5-character LED display.

**Flow/Dilution Sensors**

Transonic HD-Series Flow/Dilution Sensors use a two crystal design to pass ultrasound waves through dialysis tubing to measure blood flow and other hemodynamic parameters.

**PC-Compatible Software**

The Transonic HD02 Software captures, analyzes, and displays ultrasonic dilution curves from the HD02 Hemodialysis Monitor. The computer for these functions requires:

- Windows XP
- 256 MB RAM
- 2.0 GHz or faster Pentium processor
- 20 GB or larger hard drive
- 24X or faster CDROM
- Built-in USB Port
Accuracy

A. Delivered Blood Flow Measurements
   Range: -2 to +2 L/min
   Accuracy: ± 6% of the flow reading ± zero offset
   Maximum zero flow offset: ± 8 ml/min

B. Access Recirculation Measurements
   Range: 0 to 100%
   Accuracy: ± 2% Recirculation
             ± 3% Reading
   Repeatability: clinical correlation coefficient = 0.98

C. Access Flow Measurements
   Range: 0 to 4000 ml/min
   Accuracy: The larger error of:
             ±100 ml/min
             ±15% of reading
   Repeatability: clinical correlation coefficient = 0.98

D. Cardiac Output Measurements
   Range: 1 to 16 L/min
   Accuracy: ±0.5 L/min
             ±15% of flow reading
II. Principles of Operation

A. Continuous Monitoring of Delivered Blood Flow

The Transonic HD02 Hemodialysis Monitor uses ultrasound transit-time techniques to measure blood flow. Sensitive electronics detect the differences between upstream and downstream transit-times induced by flow.

Two transducers pass ultrasonic signals back and forth, alternately intersecting the flowing liquid in upstream and downstream directions (Figure 2). The Transonic HD02 Hemodialysis Monitor derives an accurate measurement of flow through changes in transit-times. The integrated difference between the upstream and downstream transit-times is a measure of volume flow.

During dialysis two flow/dilution sensors are attached to the blood lines, one on the venous line and one on the arterial line. The arterial Delivered Blood Flow is measured and displayed on the five-character display of the Transonic HD02 monitor.

B. Ultrasound Dilution Measurements

The velocity of ultrasound in blood (1560-1590 m/sec) is determined primarily by its protein concentration. The Transonic HD02 Hemodialysis Monitor and clamp-on flow/dilution sensors measure the velocity of ultrasound in the blood. A bolus of isotonic saline infused into the blood stream dilutes the blood, reducing ultrasound velocity. The sensors record these changes as a dilution curve. These curves are used to calculate hemodynamic parameters using the classic dilution equation for flow, \( Q = \frac{V}{S} \), where \( V \) is the amount of indicator and \( S \) is the area under the dilution curve.
Access Recirculation

Recirculation (R%) is measured by releasing saline from the saline bag for 5-6 seconds into the arterial line (before the pump) or by injecting 10ml of 0.9% NaCl solution into or before the venous bubble trap (Figure 3). The immediate appearance of a red dilution curve with area $S_{art}$ identifies recirculation (Figure 4).

The amount of injected indicator, $V_{inj}$, is proportional to the area under the concentration curve $S_{ven}$ from the venous dilution sensor multiplied by the dialyzer flow: $V_{inj} = S_{ven} Q_b$ (1). The amount of recirculated indicator, $V_{rec}$, is proportional to the area under the concentration curve $S_{art}$ from the arterial dilution sensor multiplied by the dialyzer flow: $V_{rec} = S_{art} Q_b^*$ (2). Recirculation is the ratio of the volume of recirculated indicator to the volume of injected indicator:

$$R\% = \frac{V_{rec}}{V_{inj}} \cdot 100\% = \frac{Q^*_b S_{art}}{Q_b S_{ven}} \cdot 100\%$$  (3).

![Figure 3: Normal Blood Line Configuration for Recirculation Measurement.](image)

![Figure 4: Dilution Curves Indicating 28% Recirculation.](image)
Access Blood Flow

The Transonic HD02 Hemodialysis Monitor measures Access Flow using the Krivitski Method® that involves reversing the dialyzer lines (Figure 5). The arterial inlet removing blood from the access is now downstream from the venous outlet. In this case, the flow between the needles \( Q_{\text{mix}} \) is the sum of Access Flow \( Q_a \) and dialyzer blood flow \( Q_b \), where \( Q_{\text{mix}} = Q_a + Q_b \) (4).

To measure Access Flow, saline \( V_{\text{inj}} \) is released from the saline bag for 5-6 seconds into the arterial line (before the pump) or 10ml of 0.9% NaCl solution is injected into or before the venous bubble trap (Figure 5). The area under the dilution curve \( S_{\text{art}} \) (Figure 6), recorded by the arterial sensor, is determined by the flow at the site of mixing: \( Q_{\text{mix}} = \frac{V_{\text{inj}}}{S_{\text{art}}} \) (5). The Access Flow follows from Equations 4 and 5:

\[
Q_a = Q_{\text{mix}} - Q_b = \frac{V_{\text{inj}}}{S_{\text{art}}} - Q_b \quad (6).
\]

Finally, using Equations 1 and 6:

\[
Q_a = Q_b \left( \frac{S_{\text{ven}}}{S_{\text{art}}} - 1 \right) \quad (7).
\]
Cardiac Output measurements require a 30-ml injection of body temperature (33-38°C) saline. The flow/dilution sensors measure the original signal from the saline injection as it passes the venous sensor. The saline travels through the cardiovascular system and a fraction of the original saline injection travels back to the arterial side of the vascular access. The computer analyzes the two dilution curves (Figure 7) and calculates the patient’s Cardiac Output. Several other parameters are calculated from the same dilution curve. The derivations are:

1. **Cardiac Output (CO)** measured in L/min:
   \[ CO = \frac{Q_v \cdot S_{ven}}{S_{art}} \]

2. **Cardiac Index (CI)** measured in L/min/m²:
   \[ CI = \frac{CO}{BodySurfaceArea} \]
   
   where: \( BodySurfaceArea = 0.007184 \cdot (Weight)^{0.425} \cdot (Height)^{0.725} \)

3. **Central Blood Volume (CBV)** measured in L:
   \[ CBV = CO \cdot MTT \]
   
   where: \( MTT = MTT_{art} - MTT_{ven} - T_{Tubing} \)

   \( MTT_{art} = \) mean transit time to arterial sensor

   \( MTT_{ven} = \) mean transit time to venous sensor

   \( T_{Tubing} = \) transit time in tubing

4. **Systemic Cardiac Index (SCI)** measured in L/min/m²:
   \[ SCI = \frac{(CO - Q_a)}{BodySurfaceArea} \]

5. **Peripheral Resistance (PR)** measured in (mmHg)min/L:
   \[ PR = \frac{MAP}{CO} \]
   
   where: \( MAP = \) Mean Arterial Pressure = \( \frac{(2 \cdot Diastolic \ Pressure) + Systolic \ Pressure}{3} \)

6. **Stroke Volume (SV)** measured in ml:
   \[ SV = \frac{CO}{HeartRate} \]

7. **Central Blood Volume Index (CBVI)** measured in ml/kg:
   \[ CBVI = \frac{CBV}{BodyWeight} \]
III. Installation & Testing

A. Flow/Dilution Sensor

Each Transonic flow/dilution sensor is custom designed and calibrated for use on Flow-QC tubing. Use on other tubing is possible by using the internal tubing selection list in the HD02 Dialysis Monitoring software.

Cleaning and Sterilization
The flow/dilution sensor may be cleaned by wiping with a 0.1% bleach solution or alcohol pad.

Flow/Dilution Sensor Calibration
Flow/dilution sensors are precalibrated for blood and tubing at a certain temperature. Recalibration is necessary for accurate measurements on other hemodialysis tubing. If a more precise zero baseline is needed, recalibration of sensors is necessary.

Applying the Flow/Dilution Sensor
During application of the sensors, do not hold sensors by the cable. Apply a layer of petroleum jelly (Vaseline®) in the sensing cavity of the flow/dilution sensor. The sensors must be mounted on the dialysis tubing 5 to 10 cm (2 - 4 inches) from the connection to the needle. The sensor will deform the tube slightly. For Flow-QC tubing, the sensors are placed directly on the tubing. To apply the sensor to tubing, push down on the sensor's dark gray hinge, insert tubing into the sensing cavity, and close the lid. The fit should be tight, with the full tubing circumference contacting all inner surfaces of the sensing window.

B. Laptop Setup

Plug in laptop computer and turn on the “power” switch. When Windows is running with no other programs open, proceed to Monitor Setup. Connect the monitor to the laptop using the USB cable.

C. Monitor Setup

Plug sensors into the connector on the front of the monitor. Connect the Hemodialysis Monitor to a hospital grade power source via a medical grade power cord. Turn on the "power" switch on the rear panel.
D. Cardiac Output Setup

Cardiac Output measurements require a 30-ml injection of 33-38°C saline into the injection port of the Flow-QC tubing. Follow these instructions:

1. Insert Flow-QC tubing set into the hemodialysis circuit during priming of the dialysis lines with normal saline.

2. Remove all air bubbles from the Flow-QC tubing set during priming.

3. Check to make sure sensors are placed on the Flow-QC tubing during hemodialysis.

4. When using the Transonic syringe warmer for Cardiac Output measurements, please refer to the syringe warmer instructions for use.
IV. Starting the Dialysis System Software

To start the HD02 software program, double click on the HD02 Dialysis System icon on the computer desktop.

The program will automatically countdown from 30 seconds (Figure 8). Once the timer has reached zero, the program will default to the Monitor program. During the countdown, the options are:

- Start the Monitor program (See Section V).
- Start the Administrator program (See Section VI).
- Go to Setup (See Section VII).

V. Monitor Program

To start the Monitor program, click on the large Monitor Icon. The Monitor program allows the user to measure Access Recirculation, Vascular Assess Flow and Cardiac Output.

A. Select or Add Patient

The HD02 Dialysis Monitoring Software will automatically display the Select Patient dialog box (Figure 9). To select a patient, scroll and click on a patient name or use the up and down arrow keys (If there is a large number of patients, the first letter of the patient’s last name will act as a short cut). When the appropriate patient name is highlighted, click Start Patient Session or press the Space Bar.

If you wish to exit the program, click the Exit Software Icon:
If no patients are entered or if you need to enter a new patient, click **Add New Patient** or press **F1**. You will be prompted for new patient information (Figure 10). The **Patient Information** tab requires you to enter the first and last name of the patient, patient ID and clinic. Optional information can be entered for group name, nephrologist, vascular surgeon and interventional radiologist. Click on the **Initial Access Information** tab to enter initial access type, initial access location and date of initial access placement. Click on the **Access Function Guidelines** tab to select thresholds for evaluating access function. The thresholds are used to identify a patient at risk for access failure. Select either Apply K/DOQI Guidelines or Apply Modified Guidelines. For Modified Guidelines, enter the thresholds for that particular patient. Once all the information has been entered, click **OK**. Click the **Start Patient Session** or press the **Space Bar** to start the measurement session.

### B. Patient Trends

After the patient has been selected or added, the main measurement screen will appear (Figure 11). Displayed at the top of the screen is the Patient name, ID number and patient trend graphs. The parameters that can be plotted are:

- **Access Flow Trend** – graphs the values of all access flow measurements for that patient. It also shows the intervention history (yellow triangles) and recirculation values (red diamonds) at the top of the graph.
Table of Patient Measurements - tabulates all of the measurements taken for that patient (Figure 12). The table includes date, time, mode, access type and text notes. Under the mode column, AXFLW = Access Flow, REC = Recirculation, CO = Cardiac Output and IVT = Intervention.

Cardiac Output Trend – graphs the values of all the average Cardiac Output measurements for that patient. Cardiac Output parameters from the most recent dialysis treatment can also be plotted:

- CO-CBV – graphs the values of Cardiac Output and Central Blood Volume over a 6-hour session.

- CI – graphs the values of Cardiac Index, Heart Rate and Mean Arterial Pressure over a 6-hour session.

- PR- graphs the values of Peripheral Resistance, Heart Rate and Mean Arterial Pressure over a 6-hour session.

Patient Notes – a free-form editor for entering notes on a patient or session.
D. Delivered Blood Flow

To verify Delivered Blood Flow, compare the dialysis machine setting with the measured arterial delivered blood flow displayed on the front of the Transonic HD02 Hemodialysis Monitor. The discrepancy should be within 10% of the machine setting. Factors that could produce a greater discrepancy include:

- Needle Size
- Needle Placement
- Condition of Access
- Kinked or Occluded Tubing
- Pressure Effects of the Roller Pump
- Change in Tubing Type
- Mis-calibration of Dialysis Machine or Transonic HD02 Hemodialysis Meter

E. Optional Parameters

When a measurement protocol (Access Recirculation, Vascular Access Flow or Cardiac Output) is selected, the Optional Session Parameter screen may appear (Figure 13). Appearance of this screen is dependent on which parameters are enabled in Setup. Enter the following information: systolic pressure, diastolic pressure, pump flow, Transonic pump flow, minutes into treatment, height and weight. Click OK to save.

F. Access Recirculation

To measure access recirculation, click on the recirculation icon in the lower right corner of the screen or press F9. Click on Start Protocol or press the Space Bar. When the traffic light turns green, open the pressure limits on the dialysis machine and release saline from the saline bag for 5 to 6 seconds. The software will count down from 60 seconds during the measurement process. The real-time arterial and venous signals are displayed in the bottom left corner of the screen. Once the timer has reached zero, a recirculation dilution curve and a calculated % recirculation will be displayed on the screen (Figure 14). The calculated Delivered Blood Flow (Qb) during the measurement is displayed next to the

Figure 13: Entering Optional Session Parameters.

Fig. 14: Recirculation Results Screen.
recirculation result.

G. Vascular Access Flow

To measure Access Flow, click on the Access Flow icon in the lower right corner of the screen or press F10. Stop the blood pump, reverse the blood lines and set the dialysis pump at 250-300 ml/min. When the traffic light changes to green, open the pressure limits on the dialysis machine and release saline from the saline bag for 5 to 6 seconds. The software will count down from 60 seconds during the measurement process. The real-time arterial and venous signals are displayed in the bottom left corner of the screen. Once the timer has reached zero, an Access Flow dilution curve and calculated Access Flow will be displayed on the screen (Figure 15). Under some circumstances, the software may prompt for a repeat measurement by 10-ml bolus injection in the venous bubble trap.

H. Cardiac Output

Flow-QC tubing with injection port is required for Cardiac Output measurements. Click on the Cardiac Output icon in the lower right corner of the screen or press F11. When the traffic light turns green, inject 30-ml of 33-38°C saline into the injection port. The software will count down from 60 seconds during the measurement process. The real-time arterial and venous signals are displayed in the bottom left corner of the screen. Once the timer has reached zero, the Cardiac Output dilution curve, calculated Cardiac Output, Cardiac Index and Central Blood Volume values will be displayed (Figure 16). Click on the small #2 icon next to the traffic light to display height, weight, heart rate, blood pressure, peripheral resistance, central blood volume index, systemic cardiac index and stroke volume.
VI. Administrator Program

To start the Administrator program, click on the large Administrator icon (Figure 17). The Administrator Program allows the user to modify, organize, review and print data. The main administrator software screen will appear (Figure 18). Each house icon displayed illustrates a separate clinic database. The trashcan holds deleted patient information, which can be retrieved if needed. Click on the magnifying glass next to each house icon to display the patients in that database. Click to select the desired patient. You can also use the arrow keys to scroll up and down the patient list.

A. Data Review Operations

1. Patient Trending

Graphs of all the tabulated information for a particular patient are located in the upper right hand corner of the software screen (Figure 18). The icon on the corresponding tab identifies the graphs. The graphs appear in the following order:

   Access Flow History - graphs the values of all Access Flow measurements for that patient. It also shows the intervention history (yellow triangles) recirculation values (red diamonds) at the top of the graph.

   Cardiac Output History - trending is available specifically for Cardiac Output and the derived parameters. To view a patient’s complete Cardiac Output history, select the tab with the gold heart. To view the Cardiac Output results from the last dialysis treatment, select one of the tabs with the clock icon. These graphs show the last six hours of cardiac output information, which can aide in evaluating a cardiac index profile:

   CO-CBV - graphs the values of Cardiac Output and Central Blood Volume over a 6-hour session.

   CI - graphs the values of Cardiac Index, Heart Rate and Mean Arterial Pressure over a 6-hour session.

Figure 17: Main Program Screen.

Figure 18: Main Administrator Software Screen.
PR - graphs the values of Peripheral Resistance, Heart Rate and Mean Arterial Pressure over a 6-hour session.

Patient Information - lists the following information for a particular patient: clinic, nephrologist, vascular surgeon, interventional radiologist, most recent weight, most recent access flow, most recent Cardiac Output, current access location, current access type, current access creation date, last intervention type and last intervention date.

Access History - gives the date and text note on the access history for a patient.

Patient Notes - a free-form editor for entering notes on a patient or session.

2. Statistics

Statistics work on all three levels of the database tree: clinic, group, and patient. For example, to view the statistics on a particular clinic, highlight the clinic in the tree in the upper left-hand section of the screen, and click the icon with the “i” and blue circle. This will display a window with statistics on all the measurements for the clinic (Figure 19). More specific statistics are available for each type of measurement and intervention by selecting the tabs at the top of the window for Interventions, Access Flow, Recirculation, and Cardiac Output. Highlighting an individual patient, group, or clinic will result in statistics on the highlighted entity. There is also an option to print the statistics table.

3. Identify Patients

To search the database for patients with certain criteria, click the icon with the white star and yellow circle. This feature can be used to identify patients on the alert list, identify patients by REC > 0, AXSFLW < 600 mL/min, AXSFLW > 2000 mL/min, IVT, CI <= 2.0, identify patients not measured in the last X days and identify patients not measured since a particular date (Figure 20). After selecting search criteria, click OK to search database. Each patient that matches the search criteria will have the white star and yellow circle icon next to their name. Click on Database
Operations and then View Identified Patients List. This will display all of the patients that match the criteria (Figure 21). The options are to Print List or Print Short Report.

4. Show Measurement Graphs

To review individual graphs, select the desired measurement in the table, then click on the blue and red dilution curve icon or double-click the measurement line in the table. The graph will be displayed in a new pop-up window (Figure 22). There are also options to print the graph or copy the graph to disk.
5. Reports

To generate a report for a patient, select the patient in the database. Click on the “R” with the purple circle icon. This will display a window with the type of reports possible to generate and print (Figure 23). Click on the short 1-page report, the full 5-page report or the custom report and click the print icon. This will send the patient information to the default printer. To print more than one patient at a time, press the control key (CTRL) while you select patients with the mouse. All charts for patients highlighted will print out at one time. Reports can also be generated for clinics and databases by selecting the clinic or database in the tree and clicking the “R” with the purple circle icon.

B. Database Operations

The Database Operations menu is located in the upper left-hand corner of the Administrator screen. The menu contains functions to view outside data from other clinics, files and databases. The functions from the dropdown menu include:

1. View Alert List
   This function displays a list of all patients falling below the set access flow thresholds that are entered into each patient's profile. The default thresholds are set for the K/DOQI Guideline recommendations for vascular access surveillance. There is an option to print the Alert List, print a short report of all alert list patients or to change the fistulogram referral state field. Clicking the Change Fistulogram Referral State button places a check mark next to a selected patient’s name on the Alert List to identify that the patient has been referred for a fistulogram. Click OK to exit the alert list.

2. View Logs
   This function displays daily log files as a summary of daily activity. Log files appear arranged by year. To access the log files, click on the magnifying glass next to the appropriate year, and click again on the magnifying glass next to the appropriate month. Highlight the desired day and the log file will appear on the right side of the software screen. You can print the log file by pressing the print button at the bottom of the screen or copy the log file to a floppy disk. Click OK to exit the log file.

3. View Patients by Nephrologist
   This function organizes all patients by their Nephrologist. Each green person icon indicates a separate Nephrologist. If a patient's Nephrologist is not entered, the patient will be listed under "Unknown".

4. View Patients by Vascular Surgeon
This function organizes all patients by their Vascular Surgeon. Each green person icon indicates a separate Vascular Surgeon. If a patient's Vascular Surgeon is not entered, the patient will be listed under "Unknown".

5. **View Patients by Interventional Radiologist**
   This function organizes all patients by their Interventional Radiologist. Each green person icon indicates a separate Interventional Radiologist. If a patient's Interventional Radiologist is not entered, the patient will be listed under "Unknown".

6. **View Patients by Group**
   This function organizes patients by their group. A group is defined by the end-user and is typed in the Group field under Patient Information. If the Group is not specified, the patients will be grouped under "Unknown".

7. **View Patient Trace Plus Database**
   This function views CSV files (from HD01 monitors) that may be saved on the HD02 computer or other disk drives. A browsing window is used to find, select and view a file.

8. **Import Patient Trace Plus Database**
   This function imports CSV files from existing HD01 database files into a HD02 database file. A browsing window is used to find, select and import a file (Figure 24). Type a name for a new clinic database or select an existing one from the pull down list. When importing CSV files, it is best to import into a new clinic. Importing a CSV file into an existing clinic may result in lost data. Please see Appendices A and B for complete instructions on importing data.

9. **Export as Patient Trace Plus Database**
   This function exports the HD02 database information to a PatientTrace Plus CSV file, which can be transferred to an HD01 monitor or other applications such as Microsoft Excel. To export all the data from the current database to a CSV file, select the Database menu, and scroll down to Export PatientTrace Plus Database.
Select a current CSV file to append your data to, or to create a new CSV file (Figure 25). A CSV file name will automatically be created or type over the name in the box.

10. Backup/Restore Database
To backup data, select the Backup/Restore function from the Database Operations menu. Press the New Backup button (Figure 26). It is suggested that you backup your data before using the other functions available on this screen. To restore your data to a previous date, select a date from the list of backups or press the Retrieve Backup from Floppy button and follow the on-screen instructions. After a backup is selected, you can use one of the four buttons on the right to preview, copy, restore, or delete the selection.

11. Exit Software
To exit the software program, select the Exit Software option from the Database Operations menu.

C. Clinic Operations
The Clinic Operations menu contains three functions, View Alert List, Rename Clinic and Export as Patient Trace Plus Database. View Alert List is the same function as View Alert List under Database Operations except it is for the selected clinic only. Export as Patient Trace Plus Database is the same function as Export as Patient Trace Database under Database Operations except it is for the selected clinic only.

The Rename Clinic (Figure 27) function allows you to rename a clinic in the database. To rename a clinic, select the desired clinic and select the Clinic Operations menu, and select Rename Clinic. Type the new name in the blank space provided and press the OK button. Clinics may be merged by renaming a clinic to an existing one.

D. Patient Operations
The Patient Operations Menu provides functions for modifying and deleting patients and adding notes to patients. The functions from the dropdown menu include:

1. Add Patient
The **Add Patient** function is identical to the **Add Patient** function in the Monitor program. Selecting this menu will give you a template on which to enter patient information. An entire patient roster for a clinic can be added by this method prior to using the system in the clinic.

2. **Edit Patient**
To edit patient data, highlight the appropriate patient on the clinic list in the upper left-hand corner of the screen. Select the **Patient Operations** menu and scroll down to the **Edit Patient** option. This will give you a template to edit the patient information (Figure 28). Press the **OK** button when finished.

3. **Merge Patient**
The **Merge Patient** function consolidates patients that have been entered twice, have two different ID numbers, etc. To merge patient information, select the source patient to be merged from the clinic list in the upper left-hand corner of your screen. Under the **Patient Operations** menu, select **Merge Patient**. From the next menu select a target patient to merge the information into and select **OK** (Figure 29).

4. **Delete Patient**
To delete a patient from the clinic list, select a patient from the clinic list in the upper left-hand corner of the screen. Under **Patient Operations**, select **Delete Patient**. The patient will disappear from the list and you will be prompted to confirm your decision (Figure 30). The patient’s information will be sent to the trashcan.
5. **Restore Patient**

Open the clinic database and highlight the patient to be restored. This function will restore that patient's information to the main database.

6. **New Intervention**

The HD02 Administrator program can catalog vascular access interventions. To add an intervention to a patient’s record, highlight the desired patient name on clinic list on the upper left corner of the screen. Select the **Patient Operations** menu and choose **New Intervention**. This will give you a template to enter intervention type, access location, date and text notes (Figure 31). Press the **OK** button when finished.

![Figure 31: New Intervention Menu.](image)
E. Measurement Operations

The Measurement Operations menu provides functions for modifying and deleting measurements, and adding notes to measurements. The functions from the dropdown menu include:

1. **Edit Intervention**
   To edit an intervention, select the appropriate patient from the list in the upper left-hand corner of the screen and then select the desired intervention from the list of measurements in the bottom half of the screen. The intervention entries are coded in the Mode column with a yellow IVT label. Select the Measurement Operations menu from the top of the screen and scroll down the list to **Edit Intervention**. The Edit Intervention template will appear displaying the current intervention information (Figure 32). Change the appropriate information and click **OK**.

![Figure 32: Edit Intervention Menu.](image)

2. **Add Note**
   To add a note to a measurement, select the appropriate patient from the list of patients in the upper left-hand corner on the screen. Highlight the desired measurement from the table. Pull down the Measurement Operations menu and select **Add Note** (Figure 33). Type notes in the space provided and select the **OK** button.

![Figure 33: Add Note Screen.](image)
3. **Edit Note**
   To edit a note added to a patient’s measurement list, select the line in the measurement list that contains the note. Select the **Measurement Operations** menu and scroll down to **Edit Note** (Figure 34). Make the appropriate changes to the note and click **OK** to save the information.

![Figure 34: Edit Note Screen.](image)

4. **Delete Measurement**
   This function deletes unwanted measurements, interventions, and notes. Click on the appropriate patient. Highlight the row in the bottom half of the screen containing the unwanted data. Select the **Measurement Operations** menu and scroll down to the **Delete Measurement** option. Multiple measurements can be deleted by holding down the Control key (CTRL) and selecting the desired measurements with the mouse. The measurements will disappear from the list and you will be prompted to confirm your decision (Figure 35). These deleted measurements will be sent to the trashcan.

![Figure 35: Delete Measurement Screen.](image)

5. **Restore Measurement**
   This function will restore the highlighted measurement information to the appropriate patient. Open the Trash and select the desired clinic and patient. Highlight the desired measurement and press **OK**.

6. **Move Measurement**
   The **Move Measurement** function allows you to move measurements that were performed on the wrong patient. To move measurements, select the measurements from the source patient to be moved. Under the **Measurement Operations** menu, select **Move Measurement**. From the next menu select a target patient to move the information into and select **OK** (Figure 36).

![Figure 36: Move Measurements to Existing Patient Screen.](image)
VII. Setup

To enable the setup features, click on the setup icon in the main program screen. Click on the check box next to the parameter to be enabled (Figure 37):

- **Enable Cardiac Output** – enables the Cardiac Output measurement option including specific trends and reporting capabilities.

- **Track Systolic and Diastolic Pressures** – enables the Blood Pressure and Access Resistance option.

- **Track Pump Flow** – enables the pump flow option.

- **Track Minutes into Treatment** – enables the option for how many minutes into treatment the measurement was taken.

- **Track Height & Weight** – enables the height and weight option.
  - **Calculate Pediatric Qa** – enables the option for automatically adjusting the Access Flow for pediatric patients.

Click on OK to save the settings.

**USB Procedure for HD02 Software**

The HD02 monitor has an USB connector. In order to use the HD02 system, you need to change the communication port on the HD02 laptop. Please follow these steps to make the necessary software changes:

**System Setup**

1. Plug the H4E sensors into the monitor.

2. Turn on monitor.

3. Turn on laptop.

4. Check that the HD02 software installed on the laptop is **version 1.4.2 or higher**. If it is version 1.4.1 or before, please install the newest version of the HD02 software.

5. Connect the monitor to the laptop using the USB cable.
USB Driver Setup
1. The laptop will recognize that there is new hardware by displaying the message **Found New Hardware** (for USB serial converter) on the bottom right hand corner of the screen.

![Found New Hardware](image1.png)

2. The **Found New Hardware Wizard** will be launched automatically (Figure 38).

3. Insert HD02 software CD in CD-ROM drive.

4. Click Finish to close the wizard (Figure 39).

5. The laptop will recognize that there is new hardware by displaying the message **Found New Hardware** (for USB serial port) on the bottom right hand corner of the screen.

![Found New Hardware](image2.png)

6. The **Found New Hardware Wizard** will be launched automatically (Figure 40).

7. Click Next to continue.

8. Click Finish to close the wizard (Figure 41).

9. The laptop will recognize that there is new hardware by displaying the message **Found New Hardware** (installation complete) on the bottom right hand corner of the screen.

![Found New Hardware](image3.png)

![Found New Hardware](image4.png)
Check COM Port Setting
1. To check the COM port for USB, click on the start icon and then Control Panel.

2. Double click on the System icon (Figure 42).

3. In the systems properties window, click the hardware tab and then under Device Manager, click Device Manager (Figure 43).

4. Click the ⊕ symbol next to Ports (COM & LPT) to see the COM port associated with the USB serial port (Figure 44).
Change COM Port Setting in HD02 Software

1. Double click on the HD02 Hemodialysis Icon on the desktop:

2. The monitor icon will be grayed out. Click on the Setup icon:

3. Click on the Serial Device down arrow (Figure 45) and change the serial device to the correct COM port for USB.

4. Click OK to save.

5. Exit software program.

6. Double click on the HD02 Hemodialysis icon.

7. Click on the Monitor Icon:

8. Select a patient and Start Patient Session (Space Bar).

9. Immediately after selecting Start Patient Session, the system will check for communication between the monitor and laptop. The green checkmark (Figure 46) indicates successful communication.

10. If communication fails, a warning window with a red X and a message Communicating, Please Wait (Figure 47) will appear indicating the COM port is not available and that a communication error has occurred between the monitor and laptop. Check the connections of the USB cable from the monitor to the laptop.

Note: On subsequent launches of the software, if the following warning message occurs (Figure 48), check that the monitor is on and check the connections of the USB cable from the monitor to the laptop.
XIII. Guarantee & Warranty

A. Calibration Guarantee

Transonic Systems Inc. certifies that HD02 Flowmeters and Sensors are calibrated by methods traceable to the USA National Institute of Standards and Technology (“NIST”). Transonic Systems Inc. guarantees that flowmeters will stay in calibration during their first year of use, if used and stored per standard clinical apparatus practices. Annual re-calibration is recommended. Product users may purchase additional years of recalibration service and certification.

B. Limited Warranty

Transonic Systems warrants for a period of one (1) year from date of shipment that the Flow-QC Monitor with accompanying sensors will remain free from defects which are the result of faulty material or workmanship. Transonic Systems further warrants that monitor and sensor will stay in calibration during its first year of use if used and stored per standard clinical apparatus practices. Service assurance options will extend these warranties for additional periods. Transonic Systems warrants that, upon delivery, the computer will run the supplied Flow QC Hemodialysis Monitor software. The stand-alone computer and its accessories are finished products purchased by Transonic Systems from leading manufacturers. Transonic Systems will pass the original manufacturer’s product warranty through to the first Product customer. No other warranty is expressed or implied. Transonic Systems is not liable for incidental or consequential damages. Product users may purchase additional years of warranty and repair service insurance.

Transonic Systems Inc. warranty shall not apply to: a. defects caused by abuse, neglect or misuse; (e.g., cut cable, pulled probe cable, broken sensor body due to mishandling, damaged meter cabinet); b. damage due to accident or casualty; or c. unauthorized repairs, alterations.

No other warranty is expressed or implied. Transonic Systems Inc. is not liable for incidental or consequential damages. Warranty is valid only if equipment is purchased through Transonic Systems or its duly appointed distributor or licensed representative.

C. Warranty Claim

The obligations of Transonic Systems Inc. under this warranty are limited to repairing or, at its option, replacing any goods determined to be defective. Buyer must notify Transonic Systems Inc. in writing within the warranty period of the reason Buyer believes that warranty repairs are required. Buyer must then, upon the request of Transonic Systems Inc., return the goods to the Transonic Systems Inc. manufacturing plant or to the designated service agent. Buyer pays all shipping charges. Any goods repaired or replaced by Transonic Systems Inc. shall be warranted for the period of time remaining on the original limited warranty (and its purchased extensions).

D. Equipment Return Instructions

Call your Transonic® customer service representative with a description of the problem. The customer service representative will refer you to the nearest service technician. The Service Technician will issue a
Return Merchandise Authorization (RMA) number and fax you a Flowmeter Repair Form. Completing this form with a description of the problem will assure rapid turnaround for your repair.

If possible, please use the original shipping carton for returning the monitor for repair. Include with your shipment with the power cord and flow/dilution sensors (Package all parts of the flowsensor in the original packaging).
IX. Appendices

Appendix A. Importing HD01 (Plus) Data

The Transonic HD02 Dialysis Monitoring System allows the user to import existing HD01 (Plus) patient data. The patient data in an HD01 (Plus) system is kept in the file C:\TRANHD01\ALL.CSV. This file, ALL.CSV, is a Microsoft Excel-compatible text file that has a 1-line record for every injection performed. The HD02 Dialysis Monitoring software can import this file to automatically build a new patient list and complete patient history.

The Transonic HD02 Dialysis Monitoring System does not permit importing the original dilution curve files, only the calculated result from each dilution curve file. These calculated results are stored in the ALL.CSV file.

NOTE: If you repeat this import procedure because you are importing multiple ALL.CSV files PUT EACH IMPORTED ALL.CSV INTO ITS OWN CLINIC!

HD02 Laptop Running Windows 95/98/ME/2000
1. Copy the file C:\TRANHD01\ALL.CSV from the HD01 (Plus) laptop to a floppy disk. If the file is larger than 1.4 MB (MegaBytes) than the file will not fit on a floppy disk. It will be necessary to compress the ALL.CSV file with a program such as WinZip, available at http://www.winzip.com and then copy the compressed file to the floppy disk. An installation of WinZip will be required on the HD01 (Plus) laptop to compress the file. An installation of WinZip will also be required on your HD02 laptop.
2. Insert the floppy disk containing the ALL.CSV file into the floppy drive of the HD02 laptop. To speed up the import procedure, you may copy the file A:\ALL.CSV from the floppy disk to the HD02 laptop, although this is not necessary. The actual destination of this copy process is up to you, but it is recommended to copy the ALL.CSV file to C: If you had to compress the ALL.CSV file with WinZip, then you will have to decompress the file with WinZip first before copying the file to C:
4. Once the Administrator has finished loading, click the Database Operations menu located in the upper-left corner of the screen and choose “Import PatientTrace Plus Database.”
5. The “Import PatientTrace Plus Database” dialog will appear and ask you for the name and location of the CSV file to import. If you left the ALL.CSV file on the floppy disk without copying it to the HD02 laptop, then type “A:\ALL.CSV” into the text field to the right of the “Choose CSV File” button. If you copied the ALL.CSV file from the floppy to C:, then type “C:\ALL.CSV”. If you copied the file to a different location use the “Choose CSV File” button to locate and select the CSV file.
6. Once the file has been selected, type in the name of the clinic into which this new data will be imported. DO NOT type in the name of an existing clinic and DO NOT select an existing clinic. Importing data into an existing clinic may overwrite any currently existing data within that clinic.
7. Click OK to start the import procedure.
8. If the software issues a message “Corrupt CSV! Aborting!” contact Transonic Systems, Inc. to resolve this issue.
9. Once the import procedure is completed, the software will notify you and force you to restart the software to use this imported data.
10. Proceed to Appendix B.
HD02 Laptop Running Windows XP

1. Copy the file C:\TRANHD01\ALL.CSV from the HD01 (Plus) laptop to a floppy disk. If the file is larger than 1.4 MB (MegaBytes) than the file will not fit on a floppy disk. It will be necessary to compress the ALL.CSV file with a program such as WinZip, available at http://www.winzip.com, and then copy the compressed file to the floppy disk. An installation of WinZip will be required on the HD01 (Plus) laptop to compress the file.

2. Insert the floppy disk containing the ALL.CSV file into the floppy drive of the HD02 laptop. To speed up the import procedure, you may copy the file A:\ALL.CSV from the floppy disk to the HD02 laptop, although this is not necessary. The actual destination of this copy process is up to you, but it is recommended to copy the ALL.CSV file to C: If you had to compress the ALL.CSV file with WinZip, then you will have to open the floppy disk drive from My Computer and double-click on the compressed folder with the folder/zipper icon on the floppy disk named ALL. This will open the compressed file and allow you to copy the ALL.CSV file to C:


4. Once the Administrator has finished loading, click the Database Operations menu located in the upper-left corner of the screen and choose “Import PatientTrace Plus Database.”

5. The “Import PatientTrace Plus Database” dialog will appear and ask you for the name and location of the CSV file to import. If you left the ALL.CSV file on the floppy disk without copying it to the HD02 laptop, then type “A:\ALL.CSV” into the text field to the right of the “Choose CSV File” button. If you copied the ALL.CSV file on the floppy to C:, then type “C:\ALL.CSV”. If you copied the file to a different location use the “Choose CSV File” button to locate and select the CSV file.

6. Once the file has been selected, type in the name of the clinic into which this new data will be imported. DO NOT type in the name of an existing clinic and DO NOT select an existing clinic. Importing data into an existing clinic may overwrite any currently existing data within that clinic.

7. Click OK to start the import procedure.

8. If the software issues a message “Corrupt CSV! Aborting!” contact Transonic Systems, Inc. to resolve this issue.

9. Once the import procedure is completed, the software will notify you and force you to restart the software to use this imported data.

10. Proceed to Appendix B.
Appendix B. Cleaning up Imported Data

Data imported from an HD01 (Plus) system is notorious for having multiple copies of the same patient. The HD01 (Plus) system does not question the patient information entered by the user and therefore allows several different patient names to share a single ID. The multiple copies of patients may be due to spelling mistakes in patient names or IDs; mixing up the last name and first name fields; changing the ID of a patient (this is not retroactively changed in HD01 (Plus) data); or having the same patient exist in multiple imported ALL.CSV files.

If you have imported more than one ALL.CSV
Start the Administrator. You should have multiple clinics listed in the tree; one for each ALL.CSV file you imported. Merge all of the clinics together. To do this, select a clinic and rename it to an existing clinic by using the “Rename Clinic” menu item from the “Clinic Operations” menu. If any patients share an ID, their ID will be automatically adjusted to guarantee uniqueness by prepending “TSI-x-“, where ‘x’ is a number, to their original ID. The software will notify you if IDs were automatically changed during the merge and which patients were affected.

Repeat this process until you have merged all clinics into one clinic. Proceed to the directions for having imported only one ALL.CSV.

If you have imported only one ALL.CSV
Start the Administrator. Open your one listed clinic (this clinic is the clinic you imported your ALL.CSV file into).

Error Patients
If any of the first few patients you see listed have a red patient icon, that indicates an ID conflict. Within a clinic every patient ID must be unique therefore 2 or more patients may not share the same ID. A red patient icon indicates that this patient is trying to use the same ID as another patient. This may be the result of spelling mistakes, etc, as mentioned earlier. Each red patient must be corrected one-at-a-time.

To correct a red patient follow these steps:
1. Select a patient with a red patient icon.
2. From the “Patient Operations” menu choose “Merge Patient.”
3. Locate the other patient with the same ID. If these patients are really the same, then select the target patient and click OK. Otherwise click cancel.
4. If you did not merge the patients you must edit the patient with the red patient icon to change his or her ID to be unique.

Patients with an ID starting with TSI-
These patients ID’s were automatically changed to guarantee uniqueness, but this might not be correct. Verify that every patient with an ID starting with TSI- is a unique patient. If not, then merge the patient with the TSI- ID into the correct patient following the “Merge Patient” directions.